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## **SECTION II**

### **REMARKS**

#### **Regarding the Amendments**

Claims 1, 4, 9-12, 14, 15, and 19-23 have been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

Specifically, claim 1 has been amended to incorporate the subject matter of previously pending claim 3. Claim 3 has been noted in the Office Action mailed December 10, 2007 as allowable if rewritten in independent form. As such, amended claim 1 is allowable.

By the present amendment, cancellation of claim 3 is requested, without prejudice.

Thus, upon entry of the amendments, claims 1, 4, 7-12, 14-16, and 18-23 will be pending and under examination.

#### **Claim Objection**

Claim 14 has been objected to for containing reference to a figure within the body of the claim. The examiner's attention is respectfully drawn to the Complete Listing of the Claims set forth above. As amended, claim 14 no longer contains reference to a Figure. Withdrawal of the objection is therefore respectfully requested.

#### **Rejection of Claims Under 35 U.S.C. §112**

##### **Written description**

Claims 9-12 and 19-23 are rejected in the Office Action mailed December 10, 2007 as not described in the specification in such a way as to convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the examiner objects to recitation of the claim element "crude antigen proteins extract from said microbes or antigen proteins purified from said microbes" in independent claims 9 and 19.

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The examiner's attention is respectfully drawn to the Complete Listing of the Claims as set forth above. As amended, claims 9 and 19 no longer contain the language upon which the examiner's rejection is based. As amended, claim 9 recites

"A vaccine for treating or preventing a mucosal tumor, which contains as an effective component, a microbe transformed with the vector of claim 1, expressing one or more of HPV E6 and HPV E7 antigen protein onto a cell surface, the extract from said microbes or antigen proteins purified from said microbes."

and claim 19 recites

"A vaccine for treating or preventing a mucosal tumor which includes as an effective component, the microbe of claim 16 expressing HPV E7 antigen protein onto a cell surface, the extract from said microbe or protein purified from said microbe."

Both independent claims now recite an effective component which is a microbe expressing a particular antigen protein (E6 and/or E7 in claim 9 and E7 in claim 19). Tumor-associated antigen proteins of HPV, specifically, E6 and/or E7, are described throughout the application in detail. Specific examples are provided utilizing the HPV E7 gene and one of skill in the art would have known at the time of filing, that the inventors also had possession of the HPV tumor-associated protein E6.

Applicants were clearly in possession of a microbe "expressing HPV E6 and/or HPV E7 antigen protein onto a cell surface, the extract from said microbes or antigen proteins purified from said microbes," as is presently claimed at the time of filing of the present application. The claims therefore satisfy the 35 U.S.C. §112, first paragraph, written description requirement. Withdrawal of the rejection of claims 9-12 and 19-23 as not adequately described in the specification is respectfully requested.

#### Enablement

The examiner has also rejected claims 1, 4, 7-12, and 19-23 under 35 U.S.C. §112, first paragraph as not enabled for vaccine compositions. Claim 1 is an independent claim, from which claims 4 and 7-12 depend. Claims 19-23 indirectly depend from independent claim 15.

In the second full paragraph on page 6 of the Office Action mailed December 10, 2007, the examiner states "...this rejection has not been applied to claim 3, as HPV E6 and E7 antigens are

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recognized as antigens which can elicit a protective immune response.” Applicants respectfully draw the examiner’s attention to the Complete Listing of the Claims, beginning on page 3 above, where claim 1 has been amended to recite “one or more genes selected from human papilloma virus (HPV) E6 and HPV E7 antigen protein.” Similarly, claim 19 has been amended to recite “expressing HPV E7 antigen protein.” All additional rejected claims depend from one of these claims, such that the dependent claims also contain such claim limitations.

As the claims are enabled for vaccines containing HPV E6 and/or E7, acknowledged by the examiner as eliciting an immune response, and the amended claims recite such vaccines, the presently pending claims are enabled. Withdrawal of the rejection of claims 1, 4, 7-12, and 19-23 under 35 U.S.C. §112, first paragraph as not enabled is therefore respectfully requested.

In the Office Action mailed December 10, 2007 the examiner also rejects claims 14-23 under 35 U.S.C. §112, first paragraph as not adequately described to enable one of skill in the art to make or use the invention, in that the examiner alleges that the specification lacks complete deposit information for the deposit of plasmid pHCE2LB:pgsBCA-HPVE7 and transformant KCTC 10520BP. “Evidence of public availability of the KCTC 10520BP host cells...is required.”

Applicants respectfully draw the examiner’s attention to page 25, ll. 14-17 of the application stating that applicants obtained a transformant of *E. coli* containing pGNBCA from the applicant of Korean Patent Application No. 10-2001-48373. The PCT application claiming priority to this Korean application published as WO 2003/014360. In the last paragraph of Example 1 of the published PCT application WO 2003/014360 it is stated that the expression vector pGNBCA was transformed into *E. coli* and the resulting transformant was deposited with the KCTC and assigned accession number KCTC 10025BP. Such transformant, useful in making the pHCE2LB:pgsBCA-HPV E7 transformant, is available to one of skill in the art and was available at the time of filing of the present invention. One of skill in the art would therefore be enabled to make the pHCE2LB:pgsBCA-HPV E7 transformant.

In addition, the resulting pHCE2LB:pgsBCA-HPV E7 transformant was deposited by applicants with the KCTC, an International Depository Authority under the Budapest Treaty, as KCTC 10520BP. Applicants respectfully draw the Examiner’s attention to the pages numbered 38 and 39, immediately following the claims (pages 40-43) in the published PCT application WO 2004/035795, of which the present application is a national stage filing under 35 U.S.C. §371. Provided in the published PCT application at page 39 is a Deposit Receipt showing deposit of

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KCTC 10520BP on October 7, 2003. A copy of the Deposit Receipt is attached herewith. Below is a statement by an attorney of record, that based on such Deposit Receipt, the deposit has been made to a depository authorized as an International Depository Authority under the provisions of the Budapest Treaty. Such deposit was recited in the specification as filed, however, as set forth above in the Amendments to the Specification portion of Section I of this Response, the specification has been amended to recite the date of deposit and the full street address of the depository, as provided on the Deposit Receipt. As such, the specification contains the requisite deposit information and claims 14-23 are enabled. Withdrawal of the rejection of claims 14-23 under 35 U.S.C. §112, first paragraph as lacking enablement is respectfully requested.

**Statement Regarding Deposit of KCTC 10520BP**

As an attorney of record, in reliance upon the Deposit Receipt attached hereto, the undersigned attorneys of record in U.S. Application No. 10/530,083 state that the transformant KCTC 10520 was deposited with the Korean Collection for Type Cultures (KCTC) at the Korea Research Institute of Bioscience and Biotechnology on October 7, 2003. The KCTC is a recognized International Depository Authority under the provisions of the Budapest Treaty.

**CONCLUSION**

Based on the foregoing, all of Applicants' pending claims 1, 4, 7-12, 14-16, and 18-23 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the December 10, 2007 Office Action without extension was set at three months, or March 10, 2008. In the response filed May 9, 2008, Applicants requested a two month extension of time under 37 C.F.R. § 1.136 to extend the deadline for response to and including May 10, 2008. Because May 10, 2008 falls on a Sunday, such deadline is automatically extended to Monday, May 12, 2008 through the operation of 37 CFR 1.7. Payment of the extension fee of \$230.00 specified in 37 C.F.R. § 1.17(a)(2), as applicable to small entity,

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was made on May 9, 2008 by authorization to charge the fee to a credit card. No additional fee is therefore required at this time. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

Date: 5/12/08



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Date: 5/12/08



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Enclosures:  
Receipt for Deposit of KCTC 10520BP [1 pg.]

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284

2003-10-15 10:01 FROM:

TO: 5837670

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT  
OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURE

## INTERNATIONAL FORM

## RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

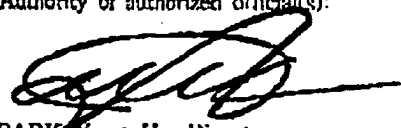
issued pursuant to Rule 7.1

TO: KOO, Haryoung

Korea Research Institute of Bioscience and Biotechnology,

#52, Oun-dong, Yusong-gu, Taejeon 305-333,

Republic of Korea

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  <b><i>Escherichia coli</i></b> <b>JM83/pHCE2LB:pgsBCA-HPVK7</b>	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  <b>KCTC 10520BP</b>
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by: <input checked="" type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on <b>October 07 2003</b> .	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depositary Authority on _____ and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____	
<b>V. INTERNATIONAL DEPOSITORY AUTHORITY</b>	
Name: Korean Collection for Type Cultures	Signature(s) of person(s) having the power to represent the International Depositary Authority of authorized official(s):
Address: Korea Research Institute of Bioscience and Biotechnology (KRIIB) #52, Oun-dong, Yusong-gu, Taejeon 305-333, Republic of Korea	 PARK Yong-Ha, Director Date: October 13 2003

Form IUPAC/ICCTV Form 171

10/12/03